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FAILURE ANALYSIS OF SOME ORTHOPEDIC IMPLANTS

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R.T. Holt, W. Wallace

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FAILURE ANALYSIS OF SOME ORTHOPEDIC IMPLANTS

(ANALYSE DE RUPTURE DE QUELQUES PROTHÈSES ORTHOPÉDIQUES)

by/par

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R.T. HOLT and/or W. WALLACE

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J.A. Dunsby, Head/Chef
Structures and Materials Laboratory/
Laboratoire des structures et matériaux

244050

G.M. Lindberg
Director/Directeur

lpg

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ABSTRACT

The latest information indicates that over 2500 orthopedic implant malfunctions may occur each year in Canada.

Several orthopedic implants which failed in service have been examined in the Structures and Materials Laboratory, National Aeronautical Establishment, National Research Council of Canada. Two classes of material were studied, wrought stainless steel, type 316L and a cast Co-Cr-Mo alloy. In each case where fracture of the device occurred, fatigue striations were detected, indicating that fatigue was a primary mechanism of failure. Other problems were detected in each class of material; corrosion in the stainless steel and porosity in the cobalt-based alloy.

Due to problems with corrosion, it is recommended that type 316L stainless steel should not be used when there is a possibility of the implant remaining in the body for an extended period of time (say over 18 months).

Also, there should be some control over the allowable porosity levels in cast cobalt-base alloys. It is shown, for example, that the porosity levels can be dramatically reduced by controlling the cooling rate during the casting process.

Recent trends in orthopedic implant technology are briefly described, particularly the processing of metal powders which gives a uniform microstructure resulting in better strength and fatigue resistance.

At the end of the report, a bibliography of over 240 papers in nine different categories covers the properties and performance of metals and alloys used as orthopedic implants.

(français au verso)

RÉSUMÉ

D'après les plus récentes données, on est amené à constater que, chaque année au Canada, quelques 2500 implantations orthopédiques se traduisent par un échec.

Plusieurs prothèses n'ayant pas donné satisfaction ont été étudiées au Laboratoire des structures et des matériaux de l'Établissement aéronautique national du Conseil national de recherches du Canada. Deux types de matériau ont été examinés: l'acier inoxydable forgé de type 316L et un alliage coulé de Co-Cr-Mo. Dans tous les cas de rupture de prothèse, on a constaté la présence de stries de fatigue, ce qui indique que la fatigue du matériau est l'un des principaux mécanismes de rupture. D'autres problèmes ont été décelés pour chaque type de matériau: corrosion de l'acier inoxydable et porosité de l'alliage à base de cobalt.

En raison de problèmes causés par la corrosion, il est recommandé que l'acier inoxydable de type 316L ne soit pas utilisé lorsqu'il est probable que la prothèse doit demeurer dans l'organisme pendant une période prolongée (plus de 18 mois à titre indicatif).

Il est aussi conseillé de contrôler d'une quelconque façon les niveaux de porosité admissibles pour les alliages coulés à base de cobalt. Il est montré, par exemple, qu'il est possible de réduire substantiellement les niveaux de porosité en agissant sur la vitesse de refroidissement du matériau pendant la coulée.

Sont enfin brièvement décrites de récentes tendances de la technologie des prothèses orthopédiques, en particulier le traitement des poudres métalliques qui permet l'obtention d'une microstructure uniforme et, par conséquent, une meilleure solidité et une résistance accrue à la fatigue.

On trouvera à la fin du compte rendu une bibliographie de plus de 240 articles classés en neuf différentes catégories qui traite des propriétés et comportement des métaux et alliages utilisés dans les prothèses orthopédiques internes.

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FAILURE ANALYSIS OF SOME ORTHOPEDIC IMPLANTS

1.0 INTRODUCTION

Over the past decade, the clinical and metallurgical evaluation of orthopedic implants has received a great deal of attention in North America and West Europe. Several review articles on the selection of materials (Refs. 1, 2, 3) and failure analysis (Ref. 4) have appeared, and minimum standards have been established by the American Society for Testing and Materials (ASTM), Canadian Standards Association (CSA) and the International Organization for Standardization (ISO).

In this report, several failures of orthopedic implants will be described. The materials were wrought stainless steel (type 316L), and a cast Co-Cr-Mo alloy.

1.1 Statistical Information on Failures in Canada

When some bone plates which had fractured in service were presented to this laboratory for analysis, one of the first questions to be asked was "is this a common problem?" The answer to that question cannot at present be answered except perhaps by individual orthopedic surgeons, for there is no single regulatory body in Canada which is responsible for the many aspects of surgical implants, including statistics on their incidence of failure.

Health data from the Provincial Governments is used by Statistics Canada in the publication of an annual catalogue entitled "Surgical Procedures and Treatments" (Ref. 5). To date, surgical operations and non-surgical procedures performed on inpatients in Canadian hospitals have been coded according to the "International Classification of Diseases adapted for use in the United States, eighth revision", often referred to as ICDA-8.

Data assembled according to this code can reveal both the approximate number of orthopedic implant operations, and the number of operations where implants are removed. Unfortunately ICDA-8 does not cover the reasons for implant removal, but a coding system used by Alberta, H-ICDA 2, includes a diagnostic clause 996.0 "malfunction of internal orthopedic device" and covers "the displacement, extrusion or fracture of a pin, plate prosthesis e.g. Austin Moore, rod or screw", but excludes infection and other non-mechanical complications of an internal prosthetic device.

H-ICDA 2 also contains a clause 78-8 covering operations involving the removal of an internal fixation device, and recent data provided by the province of Alberta for the years 1975, 1976 and 1977 are given in Tables I and II.

This information indicates:

- (i) While the number of internal orthopedic implant removals remained approximately constant during the three-year period, the ratio of malfunctions to removals increased from 24% in 1975 to 47% in 1977. The average for the three years was 37%.
- (ii) The ratio of malfunctions to removals increased markedly with age of patient. Undamaged implants are more likely to be removed from growing children and adolescents, and in older patients the removal of implants may be postponed to prevent further complications.

The latest information supplied by all provinces and published by Statistics Canada* covers the years 1975 and 1976. Data from selected codes of ICDA-8 are presented in Table III. It can be

* Starting with 1979, Statistics Canada will publish surgical procedures according to the International Classification of Diseases, ninth revision, ICD-9. Clause 996.4 of ICD-9 describes "Mechanical complication of internal orthopedic device, implant and graft", and is a broader classification than H-ICDA2, Clause 996.0

seen that the number of cases involving the insertion of an internal fixation device, (defined as a metallic screw, nail, pin, band, plate rod, prosthetic device), was about 33,600 per year. At the same time, an average of 7919 operations per year involved the removal of internal fixation devices. The Alberta figures from Tables I and II, covering only those cases listed as "primary" for the years 1975 and 1976 are also included in Table III.

If the Alberta figures are typical for the country as a whole, then about 32% of 7919 or about 2534 cases of orthopedic implant malfunctions may be expected in Canada each year. This figure is probably a conservative estimate for present-day projections because:

- (i) we have seen that the number of malfunctions reported by Alberta was even higher for 1977;
- (ii) cases where implant malfunctions were listed as a secondary diagnosis have not been included.

From the Statistics Canada information (Ref. 5) one can also calculate that the average length of stay in hospital for a patient having orthopedic implant surgery is 24.8 days. The current gross operating cost in Ontario for a hospital bed, per diem is conservatively estimated at \$170, based on a per diem cost of \$165 over the period 1 April 1978 to 31 March 1979. Therefore the total cost of replacing 2534 malfunctioning fixation devices would be about \$10.8 million per year, and if only one quarter of this money could be saved as the result of a modest research investment, then the work would be of great benefit.

1.2 Retrieval and Analysis in the USA

In 1975, a report was prepared by a team from the Utah Biomedical Test Laboratory for the Bureau of Medical Devices and Diagnostic Products, entitled "Research Evaluation of Performance Requirements for Metallic Orthopedic Implants" (Ref. 6). Of 106 retrieved implants covered in the study, 9 were removed because of mechanical failure, and the most common cause of failure was fatigue. Several recommendations for amendments to existing ASTM standards were made, and it was strongly recommended that new ASTM standards be prepared to cover packaging and labelling.

Although several ASTM standards on the design of, and materials for, surgical implants have been published in recent years there appear to be no plans to publish standards for packaging and labelling. Recently however, a Working Group has been created within ISO/TC150 to study the marking and packaging of surgical implants.

One recently published standard, ASTM F 561 entitled "Retrieval and Analysis of Metallic Orthopedic Implants", covers a procedure to be followed for complete failure analysis. As an appendix, this standard contains two forms to be completed for each retrieved implant — one by the orthopedic surgeon and the other by the metallurgist. At present there is no information on whether these forms are receiving widespread use in the USA, but this subject will certainly receive attention at the forthcoming NBS symposium on "Implant Retrieval" to be held in Washington May 1-2, 1980.

In the USA, the Food and Drug Administration (FDA) has the authority, under the Medical Devices Amendment to the Federal Food Drug and Cosmetic Act, to classify and regulate the use of orthopedic implants. A group project by students at Carnegie-Mellon University (Ref. 7) has suggested that orthopedic implant devices are too-strictly regulated because most failures were of a clinical origin. However, the group only evaluated hip implants, and of the 105 cases, 95 of the patients were over 50 years old and 68 were over 70 years old. In such cases, the load factor in terms of magnitude and number of repetitions is probably low. In 9 of the cases, complications were serious enough to warrant revised or further operations, but none of these was due to fracture of the implant.

1.3 Canadian Standards for Surgical Implants

In 1978, five CSA standards covering various metallic materials for surgical implants were approved. These standards are listed under item A 6.1 of the bibliography annexed to this report, and

are similar in technical content to both ASTM standards and ISO standards. At the present time there are no further Canadian standards proposed, but it is probable that when acceptable ISO standards are published, for example on polymers for biomedical applications, Canada will adopt ISO standards as national standards (Ref. 8).

As far as we are aware, there has been no program in Canada to determine whether orthopedic implants (most of which are manufactured in the USA) meet CSA and/or ASTM standards. Also, there has been no large-scale attempt to conduct metallurgical analysis on failed orthopedic implants. A survey of members of the Canadian Orthopedic Society is currently being conducted at Carleton University, Ottawa, (Ref. 9) and the results of this survey may help to determine the extent of the problem.

Tables IV and V list the requirements for the two alloys studied in this report according to the following CSA standards for surgical implants:

CAN3-Z310.3-78, Stainless steel sheet strip and plate,
CAN3-Z310.5-78, Cast Cobalt-Chromium-Molybdenum base alloy.

In Canada, orthopedic implants are presumably covered by the Medical Devices Regulations, Chapter 871 of the Food and Drugs Act. The general regulations cover the labelling notification and conditions of sale for a broad range of medical devices. However there appear to be no mandatory requirements that orthopedic implants meet the recommendations of either ASTM or CSA standards.

2.0 A METALLURGICAL STUDY OF SOME IMPLANT FAILURES

2.1 General Description of the Implants

A number of failed orthopedic implants was supplied to the Structures and Materials Laboratory, National Aeronautical Establishment, National Research Council of Canada, by an Ottawa hospital. Unfortunately, except for implant number 1, it was not possible to supply the medical history of either the patient or the device, but it is known that each implant was removed either because fracture had occurred, or because loosening of the implant from the bone structure had taken place. It was decided that even without the medical history, a metallurgical analysis could provide a useful assessment of failure mechanisms.

The implants are shown in Figure 1 (with the exception of implant number 3) and were of two basic alloy types: a wrought stainless steel and a cast cobalt-base alloy. Chemical analysis using the electron beam microanalyzer verified that the stainless steel was type 316 and the cobalt alloy was a Co-Cr-Mo alloy, sometimes known as HS 21 or Vitallium as described in Table IV. Since there are two surgical grades of type 316 stainless steel described in the CSA standard, each sample was subjected to carbon analysis by a combustion method where the resulting CO₂ is measured in a photometric cell by infrared absorption. It was verified that each of the stainless steels was the low carbon version, grade 2 (maximum carbon content 0.030%), also known as type 316L stainless steel. The carbon analyses, together with a brief description of each implant are given in Table VI.

For each component of each device a complete visual examination was performed, taking note of surface corrosion, machine marks, or scratches, mechanical deformation, cracking etc. and where appropriate the fracture surface was examined under a low power binocular microscope and later at high magnification in a scanning electron microscope. A brief description of each failure is given in Table VII.

Transverse and longitudinal sections were examined metallographically to determine grain size, microstructure and imperfections. The wrought stainless steels with grain sizes larger than ASTM 5.0 (the maximum grain size allowed under the CSA standards) are listed in Table VIII. Similarly, the chemical analysis results in Table VIII only include those specimens for which the chemical composition did not conform to CSA standards.

Hardness measurements are included in Table VIII for all samples even though CSA standards only specify hardness for cast Co-Cr-Mo alloys.

As noted in Table V, the CSA standard imposes a restriction on the maximum allowable non-metallic inclusion content of stainless steel orthopedic implants. In the present case the inclusions were of the globular oxide form, and were measured using Method D of the ASTM standard E45, in which the specimen at a magnification of 100 diameters is compared with a standard set of charts showing various distributions of inclusions. The inclusion content is expressed as two components, for example, the maximum allowable inclusion content "1.5 heavy" contains:

- (i) a numerical term which increases from 0.5 to 2.5 with increasing frequency of inclusions.
- (ii) the adjective "heavy" to describe a mean inclusion diameter of about $12\mu\text{m}$. "Thin" is used when the average inclusion diameter lies between 2 and $8\mu\text{m}$.

In the detailed analysis of the cast Co-Cr-Mo alloys, Section 2.3, it will be shown that the implants contained a large amount of porosity. Since there is no suitable ASTM standard, the degree of porosity has been estimated using the same ASTM E45 standard described above, because the appearance of the two forms of defect is similar. Hence for the cobalt alloys, the count given in Table VIII is mainly porosity, and since this tended to be worse in some areas, two values are given, one for a "typical" area and one for a "poor" area where the level of porosity is high. Again, the "thin" form is much less damaging than the "heavy", and even for porosity, a content of "2 heavy" is thought to be potentially damaging, while $> "2.5 \text{ heavy}"$ is unduly high.

2.2 Wrought Stainless Steel Implants

2.2.1 Implant 1, Type 316L Stainless Steel

This implant, shown in Figure 1 was an Arbeitsgemeinschaft für Osteosynthesefragen (AO) plate, used to correct a subtrochanteric fracture of the femur. The part was removed because it fractured in service only 4 to 6 months after installation, and that period included 3 months spent in recovery, during which time the load factor was probably very low. The plate was about 18 cm long, and contained a 95° corner about 5 cm from one end. In the longer section there were 9 screw holes, seven of which were 4.6 mm diameter with a countersink, while the two holes nearest the corner were 6.5 mm diameter with a small countersink, probably to allow the screw to be inserted at various angles into the bone. However, this effectively reduced the cross sectional area of the plate by 44% and it was at the second hole from the corner where failure occurred. A contributing factor could have been a bend of 9° between the second and third screw holes, probably performed by the surgeon to contour the plate to the bone. Incidentally, cracking was also discovered at the third hole and heavy crevice corrosion was found at this and other screw holes, see Figure 2. At some screw holes, including the one at which the failure occurred, no evidence of corrosion was found.

The fracture was identified as a fatigue crack which had initiated in the countersink portion of the screw hole. It is probable that surface scratches at the bearing surface of the screw acted as the fracture initiation site, shown at site A in the scanning electron micrograph (SEM) Figure 3. This failure is typical of low stress, high cycle fatigue, and at higher magnification, Figure 4, individual striations can be seen, which indicate the local progression of the crack front. The fatigue-damaged area covered both sides of the hole and it is estimated that the fatigue crack covered 80-90% of the section before overload fracture occurred.

In a polished section, as expected for a wrought product, porosity was not in evidence. The inclusion count shown in Table VIII was at an acceptable level. These inclusions were mainly oxides and some carbides, and were uniformly distributed throughout the section.

After etching in Marbles reagent*, the microstructure, Figure 5, appeared typical of a wrought stainless steel, with deformation banding, twins and a uniform grain structure. The grain size was about 60 μ m, ASTM 5.5, which is acceptable according to the CSA requirement given in Table V.

Microprobe analysis showed that the chemical composition of major elements was within the limits set by CSA standard CAN3-Z310.3-78 (see Table IV).

2.2.2 Implant Number 2, Type 316L Stainless Steel

This was a similar AO plate to that of implant number 1, but unfortunately no medical history was available. Fracture occurred at the fourth screw hole from the corner, and the fracture surface is shown in Figure 6. When viewed in the SEM, high cycle fatigue striations were observed, similar to those shown in Figure 4, and it was apparent that the fatigue crack propagated over 75% of the section before overload fracture occurred.

Corrosion products were noticed in several of the screw holes, particularly at the counter-sink.

Metallographic examination revealed an acceptable level of inclusions. The grain structure was very similar to that shown in Figure 5.

Microprobe analysis was similar to that described for implant 1.

2.2.3 Implant Number 3, Type 316L Stainless Steel

This was another AO plate similar in design to plates 1 and 2. No case history was provided, and fracture occurred at the third hole from the corner.

The crack initiation site was the top surface adjacent to the hole, and the fracture surface which is shown in Figure 7, closely resembled the two previously described, with the additional observation that corrosion products were noted on the fatigued area of the fracture surface. Heavy corrosion was noticed in several of the other screw holes.

Bone screws retrieved with implant 3 were also examined and are described in Tables VI, VII and VIII as sample 3S. The screws showed extensive corrosion at sites matching the corrosion in the screw holes. It was noticed that the screws were of the spherical headed variety similar to those described in the International Standards ISO 5835/1 and 5835/2. However, the shape of the counter-sink for this implant (and incidentally all the other implants) was conical as shown in Figure 7. Clearly this type of fit would provide ideal conditions for crevice corrosion.

It was found that the screws had a slightly higher carbon content (0.040%) than the plate, hence the screws could be classified as type 316 stainless steel or grade 1 in the CSA standard. In addition, it was found that the plate and the screws had differing microstructures with grain sizes of ASTM 4.5 and 6.0 respectively. The larger grain size in the plate does not comply with the CSA and ASTM requirements (Table V) which specify a maximum grain size corresponding to a minimum grain size number of 5.0. However, the inclusion content of the plate was one of the lowest observed.

Microprobe analysis showed wide variation in chemical composition between plate and screw. In particular, the Ni content of the plate was lower than that specified in the standard, while in the screw the Mo content was lower and the Ni content was higher than the recommended ranges.

2.2.4 Implant Number 4, Type 316L Stainless Steel

This implant was a Jewett nail used for pinning a fracture of the hip, and was removed after 2-3 years' service in a 65-year old patient when the nail became loose. There was no evidence of corrosion.

* Marbles etching solution is made by dissolving 10g CuSO₄ in a mixture of 50 ml HCl and 50 ml H₂O.

This device is of one-piece construction, yet the nail and plate portions had different metallurgical structures. The plate had a grain size ASTM 6.0 and a Vickers hardness of 239HV, whereas the nail had a grain size 6.5 and a Vickers hardness of 171HV. These differences probably reflect the varying degrees of forming to which each portion of the device was subjected during manufacture.

The microprobe analysis indicated that the chemical composition was acceptable according to the CSA standard.

2.2.5 Implant Number 5, Type 316L Stainless Steel

This plate was used for the internal fixation of a tibial or femoral fracture. It was removed after an unknown length of time when it became loose. Some of the screw holes contained corrosion products and most showed areas of wear in the countersink portion which was probably due to fretting as the screws loosened.

Metallography revealed a large grain size corresponding to a grain size number of 4.0, which is not acceptable in the CSA standard, see Table V. However, the chemical composition and the inclusion levels were both within acceptable limits according to the CSA standard.

2.2.6 Implant Number 6, Type 316L Stainless Steel

This part was the femoral portion of an AO plate which had fractured in service after an unknown period. The fracture was again by fatigue, initiating at the junction of the countersink with the top surface. Corrosion products, probably as a result of crevice corrosion, and wear marks, probably due to fretting, were observed in most screw holes.

The grain size was ASTM 6.0, which is acceptable but this material contained the highest inclusion content of all the stainless steels evaluated. However, even in the worst areas the count of "1.5 heavy" was within acceptable limits.

2.3 Cast Co-Cr-Mo Alloy Implants

2.3.1 Implant Number 7

This implant was an adjustable Smith-Peterson (S-P) plate and nail, labelled 7A and 7B respectively in Figure 1. It was used in the treatment of an intertrochanteric fracture of the femur. No other information on the patient is available, but the device was removed after fracture of the splined nail. The fracture surface is shown in Figure 8. The nail had been bent, either during installation or during service, and the spline which was under tensile stress (labelled T in Fig. 8), when examined in the scanning electron microscope, revealed high cycle fatigue striations, Figure 9a. Slip band cracking, similar to that associated with stage 1 fatigue cracking in cast Co-Cr-Mo alloys (Ref. 10) was also seen, Figure 9b.

After fatigue crack initiation, bending overload probably caused the fracture mode to change to rapid crack propagation, resulting in a fibrous surface in which one could detect patterns relating to the orientation of the underlying dendritic structure. Finally the spline on the compressive side of the nail contained a shiny faceted cleavage-like fracture which may have resulted from an extremely high crack propagation rate.

A small amount of corrosion was noted in the countersink region of one of the screw holes in the plate, but no signs of corrosion or fretting at the other screw contact points.

In polished sections, a great deal of porosity was observed, both in the nail and in the plate — see for example Figure 10. After electrolytic etching* to reveal the grain structure, grain

* Two solutions were prepared, solution A consisting of 80 ml hydrochloric acid in 20 ml water and solution B consisting of 20 ml acetic acid in 80 ml water. Electrolytic etching was conducted in a freshly prepared electrolyte (consisting of a mixture of equal parts of solutions A and B) at 2 volts for about 2 minutes.

diameters of approximately 0.7 mm in the nail and 0.55 mm in the plate were observed. The coarse dendritic structure observed was typical of a casting cooled slowly through the solidification range. Also, M_7C_3 carbides and close packed hexagonal (cph) bands were observed.

Microprobe analysis indicated that the chemical composition of the nail and the plate were both within acceptable limits as given in Table IV, although there was a difference of 1.8% in the Mo content of each component.

For comparison, an unused plate from a Smith-Peterson device was examined. This plate was identified as specimen 7N in Figure 1. The chemical composition and hardness values were found to be in the recommended ranges, but again the porosity level was very high as indicated in Table VIII.

2.3.2 Implant Number 8

This cast Co-Cr-Mo alloy bone plate fractured in service after an unknown period of time. The fracture, Figure 11, initiated at the edge of one of the screw hole countersinks, propagating across the left-hand side of the plate by fatigue, followed by overload fracture in the right-hand section. Measurements showed that the cross sectional area of the plate was reduced by 48% at the screw holes.

In the SEM, multiple crack initiation sites were observed, and one such example is shown at A in Figure 12. These sites were probably associated with porosity near the surface, and a large (18 μ m diameter) gas pore can be seen in the lower right-hand corner of Figure 12. The distribution of porosity can be better appreciated in a polished section shown in Figure 13.

Metallography also revealed a very large grain size; the average grain diameter was estimated at about 1.0 mm. The grain size variation at low magnification is shown in Figure 14. Severe cases of interdendritic shrinkage cavities were also noted.

Microprobe analysis indicated an acceptable chemical composition, and although localized variations occur in cast dendritic structures, this sample actually revealed macroscopic variations. Near the edge the average Mo content was 7.0% and Cr 29%, while near the centre the average Mo was 6.0% and Cr 31%.

While all three Co-Cr-Mo samples were within specification, it was noticed that the nickel content in each was low; the largest Ni content measured was only 0.4% compared to the allowable limit of 2.5% as shown in Table IV. Mn and Fe levels were also well below the maximum levels allowed.

2.4 Hardness Measurements

Vickers hardness (HV) measurements were made on all samples even though ASTM and CSA standards only specify hardness requirements for the cast Co-Cr-Mo alloy. All the Co-Cr-Mo alloys studied, including 7N had hardness values within the allowable range on the Rockwell C scale (HRC) of 25-34, equivalent to HV 265 to 330 - see Table VIII.

In general the stainless steels had HV values around 300, but case number 4 was much lower, around 200.

This device may not have been fully cold worked, or alternatively may have received a stress relief heat treatment.

3.0 DISCUSSION OF RESULTS

3.1 Fatigue Failure

Of the eight devices examined, six had failed by fatigue and two had been removed from service after becoming loose. Other investigations (Refs. 11, 12) have also reported fatigue to be the primary mechanism of failure in orthopedic implants.

It is clear from the case history of implant number 1 that failure occurred prematurely, and this may have also happened in other cases. From the available evidence, it cannot be established whether or not crack initiation would have occurred if the surgeon had been able to use a bone plate with a greater cross sectional area.

Bending stresses are imposed both during installation and during service of an orthopedic implant. It is not surprising that all fractures of bone plates observed in this study occurred across sections containing screw holes, for the following reasons:

- (1) The cross sectional areas were reduced by almost 50% by the presence of countersunk screw holes, and therefore any uniaxial or average bending stresses would be almost doubled.
- (2) In the bone plates studied, the screw hole diameter approximately equalled the plate thickness. For such a condition, it has been shown (Ref. 13) that bending stresses in a section containing a hole are increased by a stress concentration factor of 1.75.
- (3) Sharp corners at the countersink, together with surface defects such as galling caused by screws, scratches caused by tools, crevice corrosion pits etc. would also act as stress raisers.

Therefore, a combination of factors (1), (2) and (3) would locally raise the bending stress to a level of about four times that found at a regular cross section of the plate.

It should be emphasized that in most cases, the fatigue crack propagated over most of the cross section before overload fracture took place. This means that basically the material is strong enough to withstand the applied uniaxial or bending stress. Whereas the UTS of 25% cold-worked 316L stainless steel is about 880 MPa, the fatigue limit is only about 275 MPa, (Ref. 14) and this stress must have been exceeded in cyclic loading to cause fatigue crack propagation.

It is important that the weakest section of the plate (at a screw hole) does not coincide with the position of highest loading of the plate, usually at the bone fracture site. The plate also has a much higher modulus of elasticity than the bone, and stiffness is an important consideration at the ends of the plate where an additional bending moment may be transmitted to the bone.

These problems may be diminished by modifying the design of the bone plate so that the screw holes occupy a smaller portion of the cross section and by tapering the thickness of the plate towards the ends.

The type of bone fracture is an important consideration in the selection of the appropriate method of fixation. Seinsheimer (Ref. 15) has conducted a post-operative study on 56 patients who had received fixation devices for subtrochanteric fractures of the femur. Of these, 18 of the bone fractures had been classified by Seinsheimer as type IIIA, (3 part spiral fractures in which the lesser trochanter was part of the third fragment). Of the 56 patients, there were 8 with complications due to failure of the device, and each of those 8 had had type IIIA fractures.

The loading stress applied to an implant is related to the weight of the patient. It is not surprising that in a study of 6500 patients who received total hip replacements (Ref. 16), the incidence of implant fracture in patients weighing over 89 kg was much higher (6%) than the overall rate of implant fracture (0.23%).

With respect to the bending of implants during installation, neither ASTM nor CSA standards provide any recommendations on the extent of cold forming allowed. Nor do there appear to have been any experimental studies on the influence of cold forming on the subsequent fatigue or corrosion resistance of orthopedic implants.

3.2 Corrosion in Stainless Steel Implants

Corrosion products were discovered around screw holes in each of the stainless steel bone plates except in implant number 4. It is known that corrosion occurred in implant number 1 after a relatively short service life, and this is cause for some concern. There have been many similar reports in the literature and examples are given in References 11, 17 and 18. Stress corrosion cracking has also been cited as a failure mechanism in type 316L stainless steel (Ref. 19).

Stainless steel is particularly susceptible to crevice corrosion (Refs. 20,21) and furthermore, it has been shown (Ref. 17) that the corrosion damage is much more prevalent in multicomponent devices (such as plates attached by screws) than in single component devices (such as nails).

Recognizing corrosion as a common problem in surgical implant materials, the ASTM committee F4 held a symposium (Ref. 22) in 1978 entitled "Corrosion and Degredation of Implant Materials". Crevice corrosion and corrosion fatigue of metals used as orthopedic implants were discussed, for example type 316L stainless steel and titanium alloys, and the latter, particularly Ti-6Al-4V were reported to have superior corrosion resistance.

Since all the corrosion observed in the present study occurred in the countersink portion of the screw holes, it is assumed that the primary cause was crevice corrosion. Implant Number 3 had heavy corrosion damage and due to the fact that spherical headed screws had been used in a conically shaped countersink, a sharp crevice would have been formed between screw and plate. This effect would be further enhanced by fretting corrosion in cases where screw loosening occurred, because the continuous motion would repeatedly destroy the passive oxide film.

As reported in paragraph 2.2.3, the chemical composition of implant number 3 was different to that of the screws which had been used to attach the plate to the bone. We have not been able to find evidence in the literature that such variations in chemical composition cause galvanic corrosion. However, the molybdenum content of the screw was approximately 1.9% (i.e. was lower than the minimum requirement of 2.0% in CSA standard CAN3-Z310.3-78), and it has been shown (Refs. 23,24) that such variations in Mo content can seriously affect corrosion resistance of type 316L stainless steel in solutions containing the chloride ion.

The conditions leading to accelerated corrosive attack such as that described in paragraph 2.2.1 need to be more thoroughly investigated. For example it is possible that corrosion would be decreased if it were general practice to fabricate all components of a device from the same heat of material.

Due to problems associated with corrosion and fatigue resistance, several authors (Refs. 18, 25, 26) have suggested that surgical grade stainless steel should not be used for permanent orthopedic implants. Perhaps the appropriate CSA standards should contain a recommendation that stainless steel be used only when the implant is expected to be in service for a short period (say less than 18 months).

3.3 The Problem of Porosity in Co-Cr-Mo Alloy Castings

Each of the cast Co-Cr-Mo alloy implants studied in this project were characterized by:

- (i) extremely high porosity, which in some areas greatly exceeded the level thought to be damaging, according to Cahoon and Paxton (Ref. 27).
- (ii) A large and non-uniform grain size.

As mentioned earlier, ASTM do not have a standard for classifying porosity, and therefore acceptable levels of porosity in castings are not written into the material standards. However, it appears that some mandatory control over the allowable level of porosity would be beneficial.

Several methods for improving the structure of Co-Cr-Mo alloys are discussed below.

3.3.1 Controlling the Cooling Rate of Castings

It can be shown that both of the problems described above can be reduced by increasing the solidification rate of the cast product. Figures 15 and 16 represent two castings of a Co-Cr-Mo alloy, poured from the same heat under identical conditions. Figure 15 is a section through the neck region of a hip implant, which, due to its thickness of about 2 cm, had a fairly slow cooling rate. After casting this component was given a homogenization heat treatment, but the original dendritic structure can still be observed. The secondary dendrite arm spacing, indicated by the arrow heads on Figure 15, is about $85\mu\text{m}$, the grain size is about $650\mu\text{m}$, and a great deal of porosity is present. Based on the method of analysis described earlier in Section 2.1, the typical porosity level in this sample was "2.5 heavy", i.e. similar to that found in other cast Co-Cr-Mo alloys described in Table VIII.

On the other hand, Figure 16 represents a section through the hollow head of the same hip implant (the head had been welded to the neck), in the as-cast condition. Here the casting is about 0.5 cm thick and the cooling rate was appreciably higher. It can be seen that the secondary dendrite arm spacing (between arrow heads, Fig. 16) is now about $28\mu\text{m}$ and the level of porosity as observed in unetched specimens was drastically reduced to "0.5 thin", based on the same method of evaluation as previously described.

A further beneficial effect of faster cooling is the formation of a fine grain size which should result in greater strength.

It should be noted that the current CSA standard CAN3-Z310.5-78 describing a cast Co-Cr-Mo alloy for implants calls for minimum mechanical properties to be obtained on test samples from the same heat and cast by the same procedure as that used for the implants. However, the manufacturer is not required to demonstrate that these properties can also be obtained in test samples machined from the actual implants.

Additionally, the above-mentioned CSA standard does not specify that the implant material should be vacuum-melted and cast. This is standard practice in the aerospace industry where high quality castings are required, and perhaps the same priority should be given to surgical implants.

An extensive list of papers covering materials processing and the manufacture of metallic orthopedic implants is given in Section A2 of the bibliography at the end of this report. A brief outline of some recent developments is given below.

3.3.2 Hot Isostatic Pressing of Castings

Hollander and Wulff (Ref. 28) first showed that under certain circumstances, major improvements to properties may be obtained by the hot isostatic pressing of cast Co-Cr-Mo alloys. In this process, the casting is subjected to a high pressure treatment at high temperature, and this can cause voids to seal, while at the same time promoting strengthening by carbide precipitation and the formation of stacking faults.

However, this process is unlikely to improve the properties of:

- (a) premium quality castings which have low porosity,
- (b) castings containing excessively large pores or
- (c) air melted castings where porosity contains gases.

Consequently this process has not become standard commercial practice.

3.3.3 Heat Treatment and Thermomechanical Processing of Castings

Cast Co-Cr-Mo alloys have normally been given a solution treatment at about 1230°C to improve ductility. Clemow and Daniell (Ref. 29) indicate that this is due to a carbide transformation from M_{23}C_6 to M_6C in the narrow temperature range 1210°C to 1230°C .

Using a two-stage heat treatment with homogenization for 4 hours at 815°C and a solution treatment for 4 hours at 1225°C followed by quenching in iced brine, the properties of a cast Co-Cr-Mo based alloy were substantially improved by Cohen, Rose and Wulff (Ref. 30). Typically, the UTS increased from about 840 MPa to 1120 MPa and the elongation increased from about 11% to 25%. Further improvements in strength were demonstrated by the addition of minor alloying elements to the melt.

An even greater UTS, 1640 MPa, has been obtained by Devine and Wulff (Ref. 31) in thermomechanically treated cast ingots of a modified Co-Cr-Mo alloy, and the elongation was 26%. Also, the wrought alloy was found to have better corrosion resistance than the as-cast version.

3.3.4 Powder Processing of Orthopedic Implant Alloys

Early work by Dustdoor and Hirschhorn (Ref. 32) involved the cold isostatic pressing of type 316L stainless steel powder followed by a sintering treatment. This resulted in a porous product which allowed improved contact with the bone. This principle, to allow bone ingrowth into the implant has been further developed by the use of porous surface coatings on regular implant alloys (Ref. 33), and Deloro Stellite are producing various implants such as femoral hip implants using this process. Presumably, this type of implant would not be used if there was a possibility of removal at a later date.

More recently, the structure of Co-Cr-Mo alloys has been improved by hot isostatic pressing of the alloy powder (Refs. 34, 35). Using near net-shape processing, the cost of subsequent machining is low, and the homogeneous microstructures produced lead to greatly improved fatigue life without adversely affecting the corrosion resistance. This process is currently being used in the manufacture of orthopedic implants by Zimmer USA, under the trade name "Micro-grain Zimaloy".

3.4 Some precautions in the Use of Orthopedic Implants

An excellent description of the properties required of orthopedic implant materials has been given by Dumbleton and Black (Ref. 36). This book includes various applications for implantable materials, and the effects of these materials on body tissue.

Due to good corrosion resistance and bio-compatibility, the use of titanium alloys as implants is expected to increase markedly during the next few years. Other metallic materials such as zirconium-based alloys may also be found to be suitable for certain applications, but extensive testing would be necessary before such materials could be accepted for general use.

Since metallic implants must perform in a corrosive environment, and since cyclic loading is unavoidable, several precautions can be taken to reduce the chance of failure by corrosion and fatigue.

3.4.1 Design of Implants

- (a) Since it has been shown that the load-bearing section of a bone plate is considerably weakened by the stress raisers introduced by countersunk screw holes, perhaps modified design for bone plates could incorporate a larger net cross sectional area at the screw hole, either by widening the plate at that section, or by reducing the size of the countersunk screw holes.
- (b) Sharp corners or changes in section should be avoided if possible.
- (c) A taper towards the ends of a bone plate should reduce the problem caused by the relative difference in stiffness between the bone and the bone plate.
- (d) Spherical fitting bone screws as described in ISO standards 5835/1 and 5835/2 should provide a better fit than the conical heads described in ASTM F115. However, these screws should only be distributed for use with plates which contain spherical countersunk holes, or with plates specifically designed for spherical fitting screws such as the dynamic compression plates of the type manufactured by Zimmer and Howmedica.

3.4.2 Materials for Implants

- (a) The surface should be electropolished and surface scratches and machine marks must be avoided.
- (b) For wrought stainless steels:
 - inclusions and other defects such as laps must be avoided.
 - factors enhancing corrosion should be avoided — eg. poorly fitting screws, screws of different chemical composition to plate etc.
 - due to the high incidence of corrosion in stainless steel implants this material is only recommended for short term use.
- (c) For cast Co-Cr-Mo alloys:
 - care should be taken during component manufacture to ensure low porosity levels.
 - the grain structure should be uniform and free from shrinkage cavities.
- (d) Welds, where necessary for assembly, should be carefully examined.

3.4.3 Installation of Implants

From mechanical and metallurgical considerations, certain precautions may be taken during the installation of internal fixation devices to decrease the chance of premature failure. Important details such as ensuring that tools are made of the same material as the device, or avoidance of scarring and unnecessary bending of the device etc. are fully described in the ASTM standard F565, entitled "Standard Practice for Care and Handling of Orthopedic Implants and Instruments".

Further information in many of the techniques, fixation devices and instruments currently in common usage by orthopedic surgeons can be found in the "Manual of Internal Fixation" (Ref. 37). This book contains recommendations by the AO Group, a Swiss-based research group with an international reputation for leadership in the practice of internal fixation.

4.0 CONCLUSIONS

1. At the moment there appear to be no requirements in the Medical Devices Regulations that orthopedic implants made or sold in Canada should meet the recommendations of either ASTM or CSA standards.
2. As a result of preliminary enquiries, it has been conservatively estimated that as many as 2500 orthopedic implants may be removed prematurely in Canada each year through mechanical malfunction.
3. Several implant failures have been analyzed in this laboratory. Bone plates, both wrought stainless steel (Type 316L) and a cast Co-Cr-Mo alloy, all failed by fatigue, and all cracks propagated across sections containing screw holes. A Smith-Peterson nail made of cast Co-Cr-Mo had a low cycle fatigue-initiated failure probably followed by rapid crack growth during bending overload.
4. In agreement with other observations, the retrieved stainless steel specimens exhibited corrosion even after very short periods of service, and perhaps for this reason the use of stainless steel should be restricted to temporary implants.

5. All of the cast Co-Cr-Mo alloy parts contained high porosity, and such defects obviously weaken and embrittle the structure. It is shown that increasing the cooling rate during solidification can almost eliminate porosity, while at the same time the grain size is reduced. It is recommended that control of porosity should be included in the CSA standard CAN3-Z310.5-78.
6. Recommendations for the improved design of bone plates together with a brief discussion on recent advances in metallurgical technology have also been presented.

5.0 RECOMMENDATIONS FOR FUTURE WORK

1. The first step to be undertaken in a research program should be a comprehensive survey to determine:
 - (a) the true number of orthopedic implant malfunctions in Canada per year, together with
 - (b) the specific reasons given for each such malfunction.

At present even the most detailed coding, as used by Alberta does not specify whether malfunctions are metallurgical such as breaking, bending or corrosion, mechanical such as breakdown of cement in hip implants, or clinical such as loosening of implants during service.

2. If possible a system for the retrieval of implants should be developed in Canada either at the local, regional or national level with the aid of the appropriate authorities and orthopedic surgeons.
3. This system should preferably follow the procedure outlined in ASTM F561. However if this proves to be unworkable a simple method of collection and identification could be adopted, provided that relevant medical history could be traced for the implants of special interest.
4. Implants thus retrieved should be subject to metallurgical analysis, with a cause of failure determined for all implants which fail in service. The results should be published in a handbook with recommendations on implant design, and materials for specific applications. The work could also lead to the preparation of new or improved standards, and recent developments such as those described in Section 3.3 of this report should also be taken into consideration for future standards.
5. Further research work should be undertaken to cover the selection and development of materials suitable for implants, such as titanium- and zirconium-based alloys, together with the processing of these materials to achieve optimum strength, fatigue resistance and corrosion resistance.

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TABLE I

**SEPARATIONS FROM GENERAL HOSPITALS IN ALBERTA WITH A DIAGNOSIS OF
MALFUNCTION OF INTERNAL ORTHOPEDIC DEVICE, H-ICDA 2* CODE 996.0**

Age Group	1975		1976		1977	
	Primary	Secondary	Primary	Secondary	Primary	Secondary
0-9	1	—	—	—	2	3
10-19	14	5	20	4	24	6
20-39	35	7	44	6	53	9
40-59	34	11	65	23	72	9
60+	74	36	122	47	160	31
Total	158	59	251	80	311	58

* H-ICDA 2 is the second edition of the Hospital Adaptation of ICDA.

TABLE II

**SEPARATIONS FROM GENERAL HOSPITALS IN ALBERTA WITH AN OPERATION
INVOLVING THE REMOVAL OF AN INTERNAL FIXATION DEVICE, H-ICDA 2 CODE 78.8**

Age Group	1975		1976		1977	
	Primary	Secondary	Primary	Secondary	Primary	Secondary
0-9	37	11	33	10	47	6
10-19	170	21	135	17	134	21
20-39	235	35	222	50	267	45
40-59	115	34	119	40	127	46
60+	96	49	110	53	90	63
Total	653	150	619	170	665	181

TABLE III

ORTHOPEDIC SURGICAL IMPLANT OPERATIONS FOR 1975 AND 1976

Data Source	Code System	Code Number	Description	Cases		Total Cases
				1975	1976	
Statistics Canada (1)	ICDA 8*	Various procedures**	Insertion of internal fixation device	32487	34681	67168
	ICDA 8	80.8 procedure	Removal of fixation device (internal)	7376	8461	15837
Province of Alberta	H-ICDA 2	78.8 procedure	Removal of internal fixation device	653	619	1272
	H-ICDA 2	996.0 diagnosis	Malfunction of internal orthopedic device	158	251	409

* ICDA 8 is eighth revision of International Classification of Diseases adapted for use in the United States.

** 81.1, 81.5, 82.1, 82.3, 82.5, 82.7, 82.9, 93.2, 83.5, 84.1, 84.3, 84.5, 84.7, 87.1.

TABLE IV
CHEMICAL COMPOSITIONS OF SURGICAL IMPLANT ALLOYS ACCORDING
TO CSA STANDARDS

Material		C	Mn	P	S	Si	Cr	Ni	Mo	Fe	Co
Stainless steel, Wrought	min	—	—	—	—	—	17.00	12.00	2.00	Bal.	
	max	0.03*	2.00	0.025	0.010	0.75	20.00	14.00	4.00		
Co-Cr-Mo alloy, Cast	min	—	—			—	27.00	—	5.00	—	Bal.
	max	0.35	1.00			1.00	30.00	2.5	7.00	0.75	

* Amount shown is for Grade 2. For Grade 1 max. carbon is 0.08%.
Grade 1 is usually identified as type 316 stainless steel.
Grade 2 is usually identified as type 316L stainless steel.

TABLE V
METALLURGICAL REQUIREMENTS OF ALLOYS ACCORDING TO CSA STANDARDS

Material	Condition	UTS (MPa)	0.2% Offset Yield (MPa)	Elongation (%)	Hardness (HRC)	Grain Size (ASTM E112)	Maximum Inclusion Content (ASTM E45)
Stainless Steel, Wrought, Grade 1	Annealed	515	205	40	—	5 or finer	globular oxide type, "1.5 heavy"
	Ann. + cold finish	620	310	35			
	Ann. + cold work	860	690	12			
Co-Cr-Mo, Cast	As cast and Machined	655	450	8	25-34	—	—

TABLE VI

IDENTIFICATION OF RETRIEVED IMPLANTS

Implant Case Number	Material	Part or Location	Form (rod, plate, screw etc.)	Service Time (if known)
1	316L ss carbon 0.029	femur	AO plate	~ 5 mo.
2	316L ss carbon 0.029	femur	AO plate	
3	316L ss carbon 0.030	femur	AO plate	
3s	316 ss carbon 0.040		screw from AO plate 3	
4	316L ss carbon 0.028	hip	Jewett nail	2-3 yr.
5	316L ss carbon 0.029	tibia or femur	plate	
6	316L ss carbon 0.020	femur	AO plate	
7A	cast Co-Cr-Mo alloy	intertrachanteric fracture of femur	HSP plate	
7B	cast Co-Cr-Mo alloy	intertrachanteric fracture of femur	HSP nail	
8	cast Co-Cr-Mo alloy	bone plate		

AO = Arbeitsgemeinschaft für Osteosynthesefragen

HSP = Howmedica adjustable Smith-Peterson

ss = stainless steel

cw = cold worked.

TABLE VII
DESCRIPTION OF FAILURES

Implant Case Number	Reason for Removal	Location of Failure	Mode (s) of Failure	Comments
1	implant fracture	screw hole	F, possibly CF	screw hole damaged
2	implant fracture	screw hole	F	
3	implant fracture	screw hole	F	
3s	removed with plate no. 3	—	—	
4	became loose	—	—	very little corrosion
5	became loose	—	—	very little corrosion
6	implant fracture	screw hole	F (high cycle)	crevice corrosion observed
7A	removed with 7B	—	—	
7B	implant fracture	surface initiation	F	low ductility
8	implant fracture	screw hole	F	possibly initiated by porosity

F = fatigue
CF = corrosion fatigue

TABLE VIII
RESULTS OF METALLURGICAL EXAMINATION

Implant Case Number	Deficiency of implants cf. CSA Standards		Vickers Hardness (HV) (20 kg)	Rockwell Hardness (HRC)	Inclusion + Porosity* Count			
	Microstructure	Chem. Comp.			Area	Type	Series	Count
1			T 333 L 326		typical	D	thin	1.5
					poor	D	heavy	1.5
2			T 300 L 306		typical	D	thin	1.5
					poor	D	heavy	2.0
3	GS 4.5	Ni 11.5 (low)	T 295 L 302		typical	D	thin	1.0
					poor	D	thin	1.5
3s		Mo 1.88 (low) Ni 15.2 (high)	327		typical	D	heavy	1.5
					poor	D	heavy	1.5
4			plate 235 nail 171		typical	D	thin	0.5
					poor	D	heavy	1.0
5	GS 4.0		T 318 L 327		typical	D	thin	0.5
					poor	D	thin	1.0
6			T 288 L 281		typical	D	thin	1.5
					poor	D	heavy	1.5
7A			T 273 L 296	T 26.0 L 29.2	typical	D	heavy	2.5
					poor	D	heavy	>> 2.5
7B			291	28.5	typical	D	thin	2.5
					poor	D	heavy	> 2.5
7N			T 287 L 287	T 28.0 L 28.0	typical	D	heavy	2.0
					poor	D	heavy	> 2.5
8			T 272 L 283	T 25.9 L 27.5	typical	D	heavy	2.5
					poor	D	heavy	> 2.5

GS = Grain size (ASTM). Max. grain size allowed is 5.0.

T = Transverse section.

L = Longitudinal section.

* Porosity was only observed in the cast Co-Cr-Mo alloys. The count was made using ASTM-E45, Plate III, Method D, Globular Oxide.

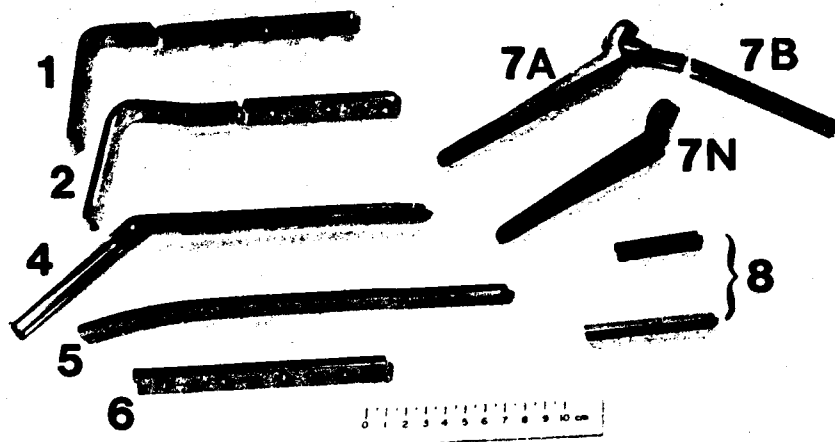


FIG. 1: STAINLESS STEEL (ON THE LEFT) AND COBALT ALLOY IMPLANTS, AS RECEIVED FOR STUDY. IMPLANT NUMBER 3 (NOT SHOWN) WAS SIMILAR TO IMPLANT NUMBER 2

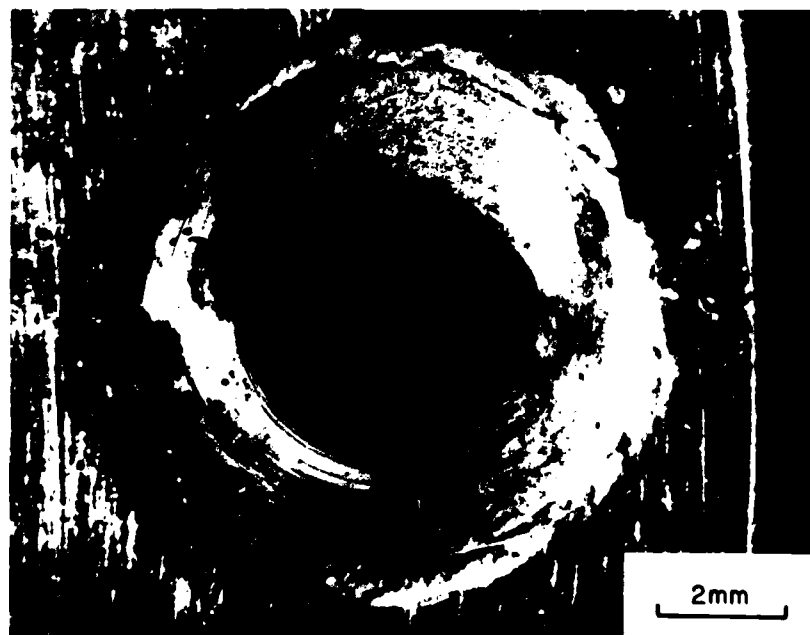


FIG. 2: CREVICE CORROSION AROUND A SCREW HOLE IN IMPLANT NUMBER 1

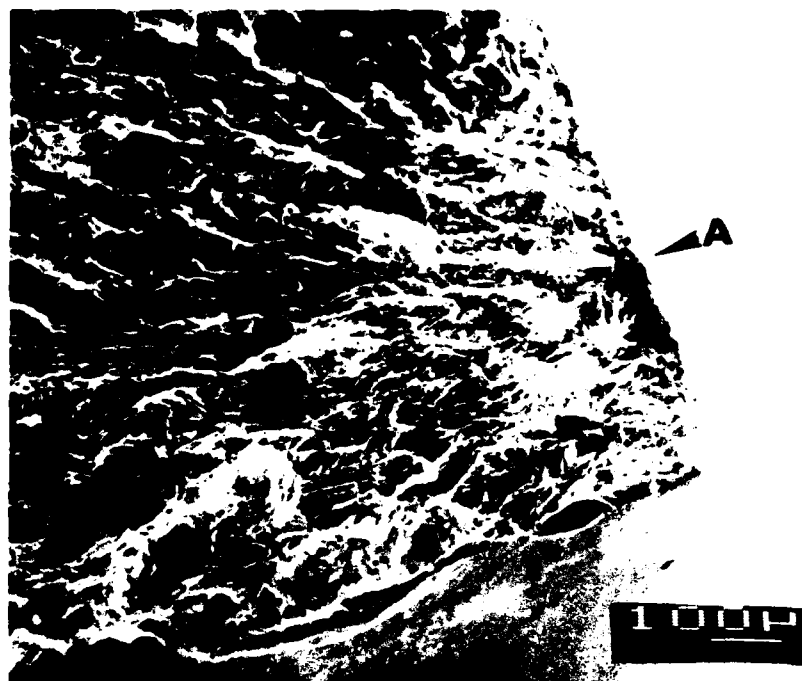


FIG. 3: SCANNING ELECTRON MICROGRAPH SHOWING
THE CRACK INITIATION SITE 'A'
AT A SCREW HOLE IN IMPLANT NUMBER 1

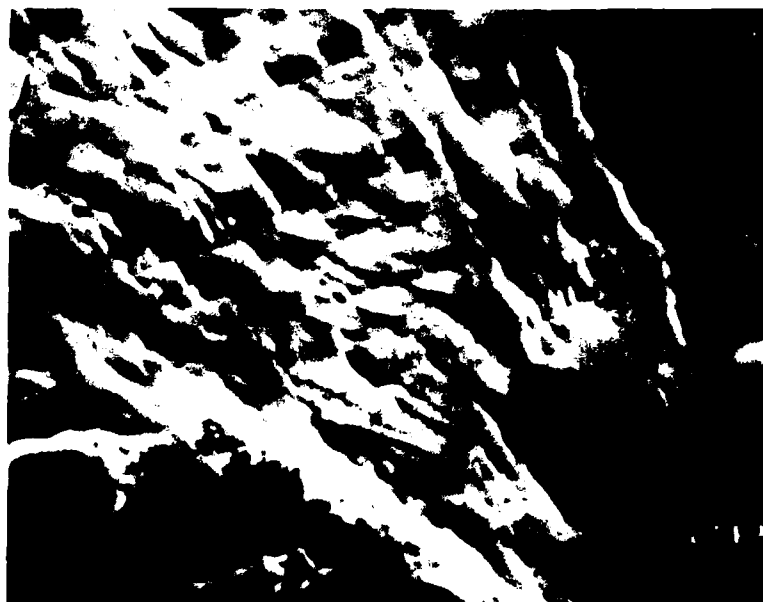
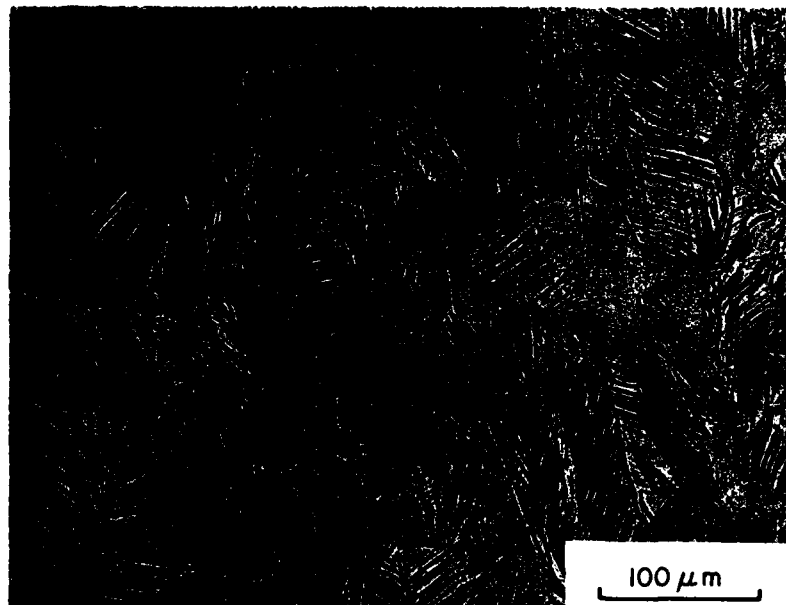


FIG. 4: FATIGUE STRIATIONS IN THE FRACTURE SURFACE
OF IMPLANT NUMBER 1



**FIG. 5: THE MICROSTRUCTURE OF IMPLANT NUMBER 1,
TYPICAL OF A WROUGHT STAINLESS STEEL**

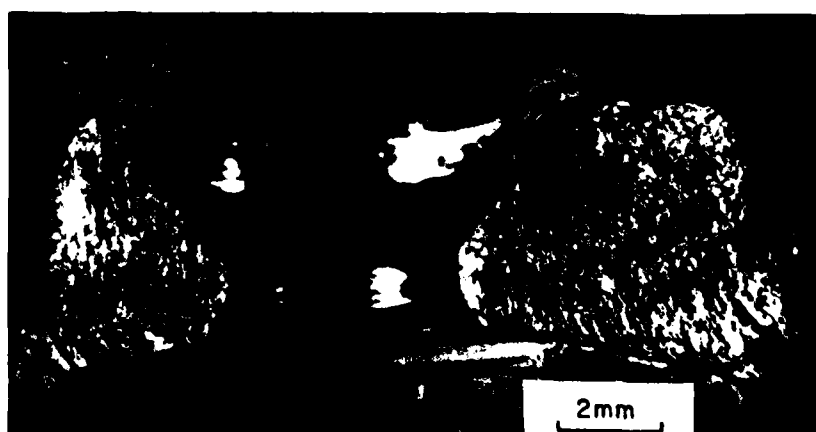


FIG. 6: THE FRACTURE SURFACE OF IMPLANT NUMBER 2

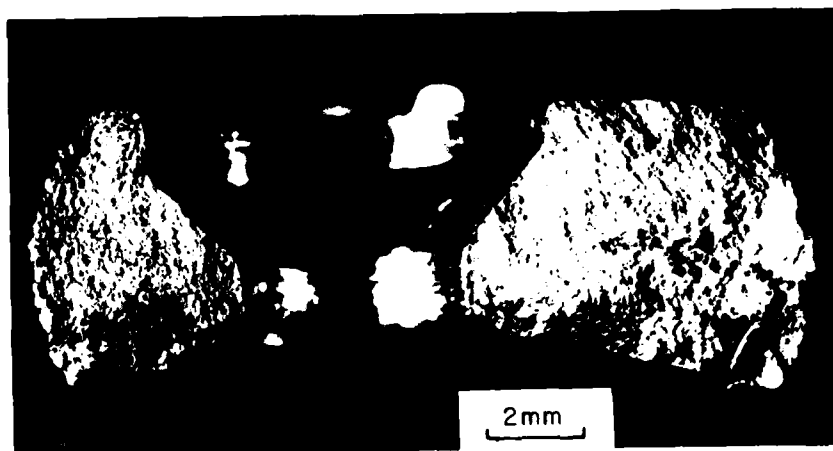


FIG. 7: THE FRACTURE SURFACE OF IMPLANT NUMBER 3

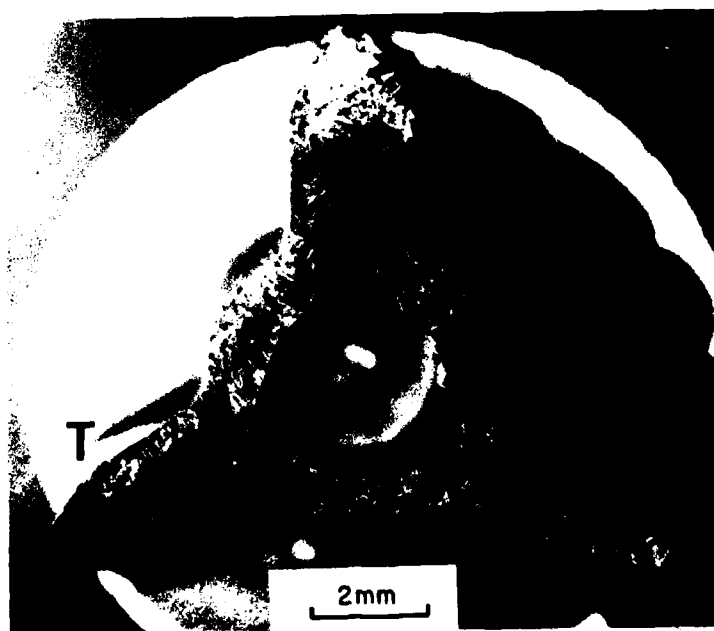
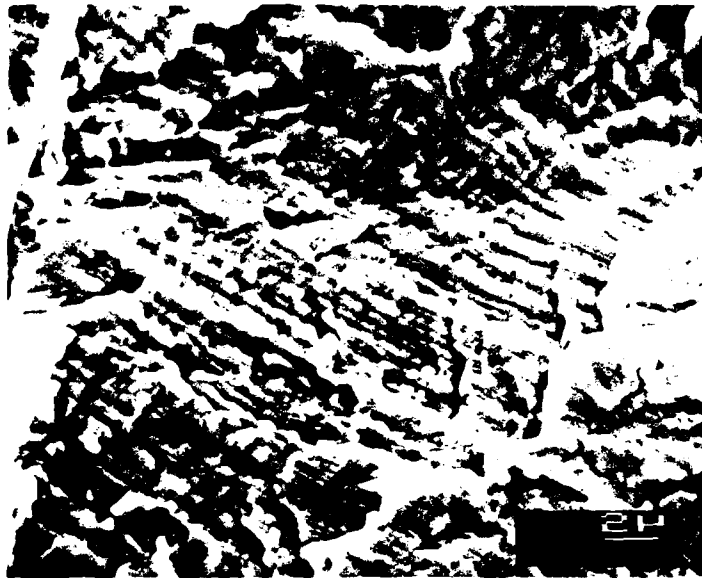
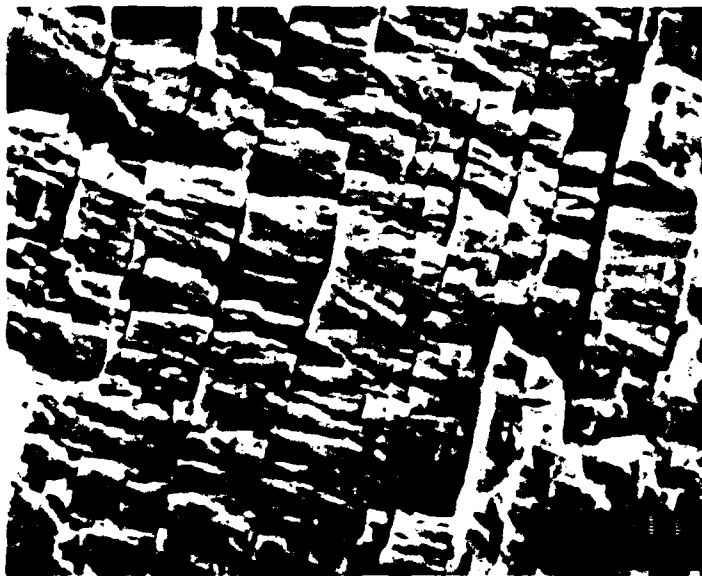


FIG. 8: THE FRACTURE SURFACE OF IMPLANT NUMBER 7B



(a) FATIGUE STRIATIONS



(b) SLIP BAND CRACKING

FIG. 9: SCANNING ELECTRON MICROGRAPHS OF THE FRACTURE IN IMPLANT NUMBER 7B

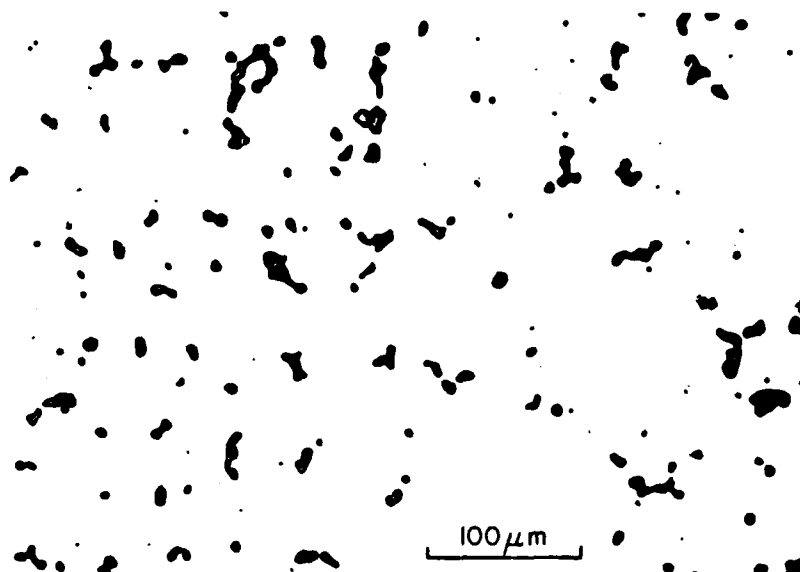


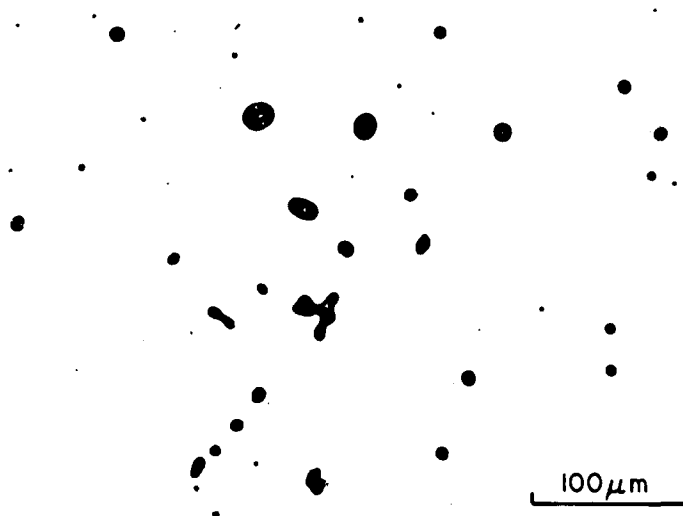
FIG. 10: POROSITY IN A POLISHED SECTION
OF IMPLANT NUMBER 7A



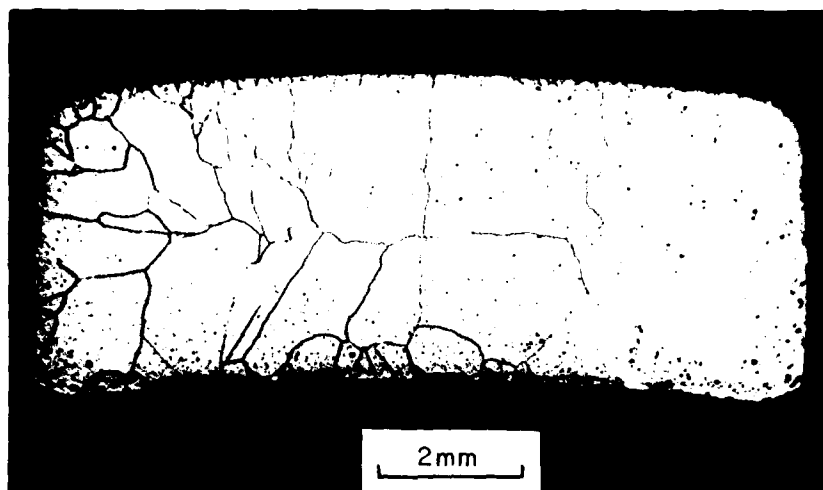
FIG. 11: THE FRACTURE SURFACE OF IMPLANT NUMBER 8



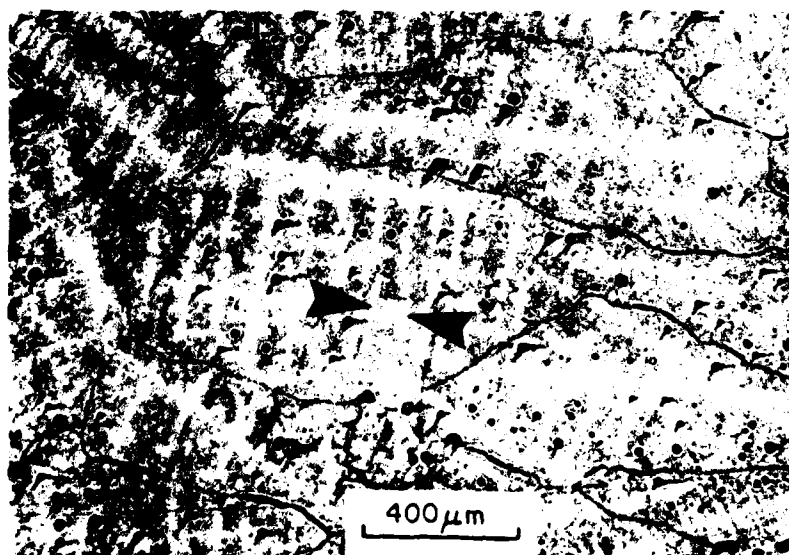
**FIG. 12: SCANNING ELECTRON MICROGRAPH OF A TYPICAL
CRACK INITIATION SITE IN IMPLANT NUMBER 8**



**FIG. 13: POROSITY IN A POLISHED SECTION
OF IMPLANT NUMBER 8**



**FIG. 14: GRAIN SIZE VARIATIONS IN A SECTION
OF IMPLANT NUMBER 8**



**FIG. 15: SECTION THROUGH A SLOWLY COOLED Co-Cr-Mo ALLOY
CASTING AFTER HEAT TREATMENT
THE ORIGINAL SECONDARY DENDRITE ARM SPACING IS SHOWN
BETWEEN ARROW HEADS**

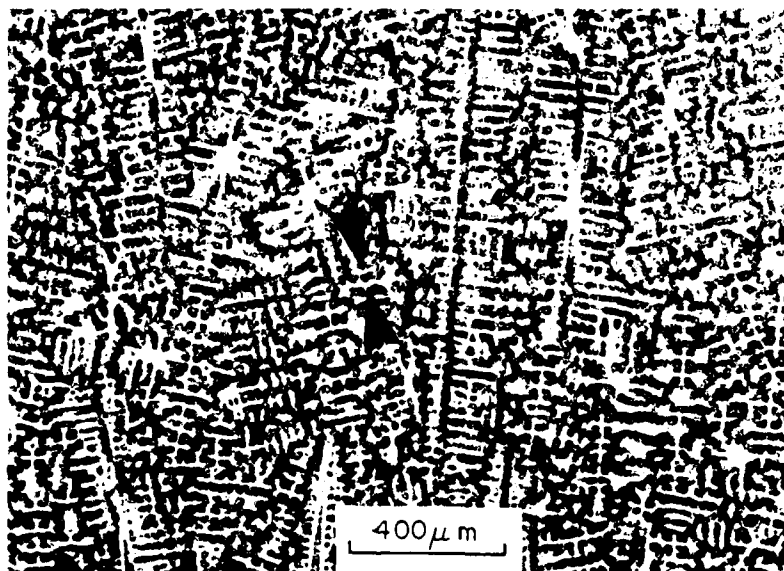


FIG. 16: THE SAME ALLOY AS SHOWN IN FIGURE 15
BUT COOLED AT A FASTER RATE
NOTE THE DECREASED SECONDARY DENDRITE ARM SPACING
AND THE REDUCED LEVEL OF POROSITY

ANNEX A

BIBLIOGRAPHY ON THE USE OF METALS AND ALLOYS FOR ORTHOPEDIC IMPLANTS

The following is a list of publications from 1968 to present which is of interest to anyone working in the field of metallic orthopedic implants. All papers are in English unless otherwise stated.

The papers have been grouped under the following headings:

- A1 Evaluation of Metals and Alloys used for Orthopedic Implants
 - A1.1 Review Articles, Refs. 1-9
 - A1.2 General Assessment of Implant Materials, Refs. 10-33
 - A1.3 Corrosion Resistance, Refs. 34-85
 - A1.4 Fatigue Resistance, Refs. 86-97
 - A1.5 Wear Resistance, Refs. 98-112
- A2 Materials Development, Material Processing, and the Manufacture of Implants, Refs. 113-140
- A3 Implant Evaluation, Stress Analysis, Design, Refs. 141-168
- A4 Porous Surface Coatings, Refs. 169-190
- A5 Orthopedic Implant Retrieved and Analysis, Refs. 191-242
- A6 Current Standards for Implant Design and Materials
 - A6.1 CSA Standards
 - A6.2 ASTM Standards
 - A6.3 ISO Standards

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A6 Current Standards for Implant Design and Materials

A6.1 Canadian Standards Association (CSA)

CAN3-Z310.1-78	Titanium Alloy (6% Aluminum and 4% Vanadium) for Surgical Implants
CAN3-Z310.2-78	Stainless Steel Bar and Wire for Surgical Implants
CAN3-Z310.3-78	Stainless Steel Sheet, Strip, and Plate for Surgical Implants
CAN3-Z310.4-78	Wrought Cobalt-Chromium-Tungsten-Nickel Alloy for Surgical Implants
CAN3-Z310.5-78	Cast Cobalt-Chromium-Molybdenum Base Alloy for Surgical Implants

A6.2 American Society for Testing and Materials (ASTM)

A large number of standards may be found in the ASTM Index, 1979 edition part 48 under the following general headings:

Bone bolts, nails, plates, screws, staples
Cranioplasty plates
Intramedular nails, pins, rods
Prostheses
Surgical Implants.

A6.3 International Organization for Standardization, (ISO)

ISO Standards may be found in the ISO Catalogue, 1980 edition under the heading of TC 150, Implants for Surgery.

NRC, NAE MS-143

National Research Council Canada. National Aeronautical Establishment.

FAILURE ANALYSIS OF SOME ORTHOPEDIC IMPLANTS.

R.T. Holt and W. Wallace. May 1980. 56 pp. (incl. tables and figures).

The latest information indicates that over 2500 orthopedic implant malfunctions may occur each year in Canada.

Several orthopedic implants which failed in service have been examined in the Structures and Materials Laboratory, National Aeronautical Establishment, National Research Council of Canada. Two classes of material were studied, wrought stainless steel, type 316L and a cast Co-Cr-Mo alloy. In each case where fracture of the device occurred, fatigue striations were detected, indicating that fatigue was a primary mechanism of failure. Other problems were detected in each class of material; corrosion in the stainless steel and porosity in the cobalt-based alloy.

Due to problems with corrosion, it is recommended that type 316L stainless steel should not be used when there is a possibility of the implant remaining in the body for an extended period of time (say over 18 months).

Also, there should be some control over the allowable porosity levels in cast cobalt-base alloys. It is shown, for example, that the porosity levels can be dramatically reduced by controlling the cooling rate during the casting process.

Recent trends in orthopedic implant technology are briefly described, particularly the processing of metal powders which gives a uniform microstructure resulting in better strength and fatigue resistance.

At the end of the report, a bibliography of over 240 papers in nine different categories covers the properties and performance of metals and alloys used as orthopedic implants.

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